SEP 27 2012

510(k) Summary for the
Lutronic Corporation FREEDOM Laser System

This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. **General Information**

Submitter:	Lutronic Corporation Room 403-1, 2, 3, 4, 5, 404 Ilsan Technotown 1141-1 Baekseok-dong, Ilsandong-gu, Goyang-si, Gyeonggi-do, 410-722 Republic of Korea
Contact Person	Jhung Won Vojir, Ph.D. Chief Executive Officer Lutronic, Inc. Six Neshaminy Interplex, Suite 207 Trevose, PA 19053 jvojir@lutronic.com Tele: 215-205-2219 FAX: 609-488-6958
Summary Preparation Date:	December 27, 2011

2. **Names**

Device Name:	FREEDOM Laser System
Classification Name:	Laser instrument, surgical, powered device: GEX FDA Class II category

3. **Predicate Devices**

The FREEDOM Laser System is substantially equivalent to the Cutera GenesisPlus (K103626).

4. Device Description

The FREEDOM Laser System consists of a self-contained console, an optical fiber delivery system and a footswitch. The system console is the heart of the FREEDOM Laser System and contains the Nd:YAG optical system, laser system control, fiber delivery system with handpiece, system control module with an embedded processor, and power supply module. The main console also includes a key switch used to turn the power on and off, an emergency stop push button that quickly de-energizes the system in emergency situations, and the LCD display.

5. Indications for Use

The FREEDOM Laser System is intended for the following:

Intended for use in the medical specialties of general and plastic surgery, dermatology, endoscopic, laproscopic general surgery, gastroenterology, gynecology, otorhinolaryngology (ENT), neurosurgery, oculoplastics, orthopedics, pulmonarythoracic surgery, podiatry and urology for surgical and aesthetic applications.

For intended use in Dermatology for the coagulation and hemostasis of benign vascular lesions such as, but not limited to, rosacea, poikiloderma of civatte, and treatment of benign cutaneous lesions, such as warts, scars and straie. Also intended for the treatment of wrinkles such as, but not limited to, periocular and perioral wrinkles.

For intended use on all skin types (Fitzpatrick I-VI), including tanned skin.

For intended use in Podiatry for the ablation, vaporization, incision, excision, and coagulation of soft tissue, including Matrixectomy, Periungual and subungual warts, Plantar warts, Radical nail excision, Neuromas.

For intended use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes, Trichophyton rubrum and T. mentagrophytes, and/or yeast Candida Albicans, etc.).

6. Substantial Equivalence

The FREEDOM Laser System is substantially equivalent to the Cutera GenesisPlus (K103626. The intended use and technological characteristics of the FREEDOM Laser System are identical to the intended use and technological characteristics of the predicate devices. Therefore, the FREEDOM Laser System is substantially equivalent the predicate device.

7. Performance Data
None presented.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 13, 2013

Lutronic Corporation
% Lutronic Incorporated
Ms. Jung Won Vojir
Global Regulatory Officer
6 Neshaminy Interples, Suite 207
Trevose, Pennsylvania 19053

Re: K113843
Trade/Device Name: FREEDOM Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: PDZ, GEX
Dated: September 5, 2012
Received: September 6, 2012

Dear Ms. Vojir:

This letter corrects our substantially equivalent letter of September 27, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,
FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113843

Device Name: FREEDOM Laser System

Indications for Use:

Intended for use in the medical specialties of general and plastic surgery, dermatology, endoscopic, laproscopic general surgery, gastroenterology, gynecology, otorhinolaryngology (ENT), neurosurgery, oculoplastics, orthopedics, pulmonarythoracic surgery, podiatry and urology for surgical and aesthetic applications.

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Prescription Use X AND/OR Over The Counter Use _
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) for mKm

Page 1 of 1 (Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K113843